PLAINTIFF'S EXHIBIT NO. 23 (03.07.17 HEARING)

USDA

Overall Summary and Recommendation(s)

Liguria Foods, Inc. is a small facility (in HACCP terms) that produces ready to eat (RTE) fermented meat products. They receive raw beef and pork products that are ground then fermented, heated, and dried. All products are identified as consumer ready and have a shelf life 9 months at >40°F and indefinite if refrigerated or frozen, no allergens are used in products currently produced at this facility.

During the Comprehensive Food Safety Assessment, the written sanitation program, SSOP documentation, and program implementation was reviewed. The development and implementation of the company's SSOPs, SOP, GMPs, and other pre-requisite programs are intended to meet the requirements of 9 CFR 416. Noncompliance with the requirements of 9 CFR 416.1-416.4 was not observed.

Liguria Foods has developed written programs that contain procedures to be conducted daily to ensure sanitary conditions are established and maintained with the following exceptions: some equipment is not available for cleaning prior to production and is not addressed in the written program including smokehouse carts, sticks, product peeling tables, and formulation tubs however, records were provided documenting the cleaning. NR# was issued for failure to meet the requirements of 9 CFR 416.12(a).

Implementation of the sanitation procedures and sanitary conditions of the plant were observed prior to and during operations. No insanitary conditions were observed. The company conducts sampling to demonstrate that sanitary conditions are established in the facility. RODAC results were reviewed and were below the established limit. Pre-operational monitoring was observed, equipment was disassembled for cleaning and inspected as stated in their written program, and the areas were cleaned and sanitized prior to operating.

Records reviewed indicate the establishment is maintaining adequate documentation to demonstrate the implementation, monitoring, and corrective actions taken in regards to the SSOP's with the following exception: Operational deficiencies records include incomplete corrective actions, product disposition was not included. This finding was discussed with Jim Whitham. He stated that the product was cooked per the Alternative Corrective Action program, which states the product, will be cooked to 160°F for 5 minutes. These records were provided for review and contained the necessary information to indicate the Alternative Corrective Actions were implemented. The SSOP records do not adequately document product disposition as required thus not meeting the requirements of 9 CFR 416.16(a) NR# was issued for this finding.

Based information gathered during review of the written programs and associated records as well as observations during the CFSA, the company has developed written programs and or maintained records adequate to address sanitary conditions at the facility. The non-compliance identified indicates clarification is needed in the written program and complete product disposition information on the SSOP records when corrective actions are taken. Other supporting documents were provided sufficient to conclude there is not a food safety concern with these findings.

Documents reviewed at Liguria Foods, indicate a hazard analyses was conducted to determine the food safety hazards reasonably likely and not reasonably likely to occur in their process. The Shelf Stable Dry Sausage HACCP Plan was reviewed, all hazards reasonably likely to occur are appropriately identified, and sufficient controls are in place.

The company conducts raw product testing as well as environmental and finished product testing demonstrating the bacterial loads on the product are not excessive, sanitation procedures are adequate and finished products are within the established limits. A challenge study was conducted by Silliker, Inc. Food

Science Center in July 2011 to validate the current process. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

Review of the HACCP plan and associated supporting documents indicate the HACCP plan has been adequately developed with the following exceptions; The HACCP plan does not include direct observation of corrective actions. Also the written program states: "reviews will be considered to be successful if a NR/deviation report is not filled out". The HACCP records do not include results as required. A noncompliance with 9 CFR 417.2(c)(7) and 9 CFR 417.5(a)(3) which were documented on XXXX.

The noncompliance observed do not result in food safety concerns based on observation that procedures are being appropriately implemented. Based on all information reviewed the company has developed an adequate food safety system sufficient to produce safe and wholesome product supporting the recommendation that noncompliance found be addressed with a NR.

General Sanitation: SPS and SSOP

GS1 **Is the building maintained in a sound condition as described in 9 CFR 416 (e.g., no leaks, wall integrity good, no standing water)?**

___X___ Yes
_____ No

GS1a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Areas of the facility, including the production rooms were observed prior to and during operations. The walls and ceilings in the facility are constructed of durable, impervious, cleanable materials, and maintained in good repair. All floor drains observed were functioning adequately to prevent the creation of insanitary conditions, no standing water was observed. The grounds about the facility are maintained in a manner sufficient to prevent conditions that could lead to the harborage of pests. Production areas observed had sufficient lighting. Observations indicate the building is maintained in sound condition.

GS2 **When was the main "brick and mortar" structure of the premises built?**

_____ Before 1960
___X___ 1960-1970
_____ 1970-1980
_____ 1980-1990
_____ 1990-2000
_____ 2000-Present

GS3 **Is the equipment free of cracks, pitting, rust or other defects that could affect cleaning and sanitizing procedures?**

___X___ Yes
_____ No

GS3a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** During the assessment, equipment was observed before and during production, no defects that could preclude cleaning were identified.

GS4 **Are there any findings during the course of the FSA that raise a concern as to whether the sanitation system is adequate to meet the sanitation performance standard requirements (e.g. ventilation, condensation, structural integrity)? (Question GS4 refers to all of the Sanitation Performance Standards, covered under 416.1-416.4)**

_____ Yes
___X___ No

GS4a Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision. Briefly describe your observations and any non-compliance with the SPS regulations.

Ongoing maintenance is conducted to improve the facility. Water and sewage are provided by the city of Humboldt, a current water potability certificate is on file. The exterior of the establishment is maintained in a manner sufficient to prevent pest harborage. Presto X Pest Management Services conducts weekly checks for rodents and insects inside and outside the facility and provides service reports to plant management. Service Reports from 4/18/2011 through 01/09/2012 were reviewed and indicate pest infestation is not an issue at this facility. All chemicals used for pest management are identified and MSDS information is on file. In discussion with plant management, as well as observations during production it was determined that water is not reused in this facility. Dressing rooms, lavatories, and toilets were observed and maintained in a sanitary manner. Hand tools used in production were observed and are made of cleanable materials and stored in the production area when not in use. Inedible materials are placed in receptacles, which are clearly identified. Observations of the facility before and during operations revealed no SPS noncompliance. Observations and review of company documents demonstrate the requirements of 9 CFR 416.1-416.4 are being met at this time.

GS5 Are the SSOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product?

_____ Yes
___X___ No

GS5a Are the sanitation SOPs signed and dated?

___X___ Yes
_____ No

GS5b Are the pre-operational sanitation procedures identified as such?

___X___ Yes
_____ No

GS5c Do the procedures in the Sanitation SOP address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils?

___X___ Yes
_____ No

GS5d Do the Sanitation SOPs specify the frequency with which each procedure in the Sanitation SOPs will be conducted and do they identify the establishment employee responsible for the implementation and maintenance of such procedures?

___X___ Yes
_____ No

GS5e **For GS5-GS5d, why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** A program titled Standard Sanitation Operating Procedures was reviewed. This programs was reevaluated and signed by Jim Whitham, QA Manager on December 13, 2011 and contains pre-operational and operational sanitation procedures to be conducted daily. The requirements of 9 CFR 416.12(b) and 416.14 are being met at this time. However, some equipment is not available for cleaning prior to production and is not addressed in the written program. (i.e. smokehouse carts, sticks, product peeling tables, and formulation tubs). The cleaning of these items is documented by the employee conducting the task. These records were reviewed and adequately document the cleaning. NR# was issued for failure to meet the requirements of 9 CFR 416.12(a). The written program includes the following information: Each supervisor is responsible for training and monitoring compliance with SSOPs and the QA Manager or designee is responsible for daily verification. Pre-operational procedures are identified as such and indicate cleaning and sanitizing of all product contact surfaces of equipment and utensils will be conducted prior to the start of production. The requirements of 9 CFR 416.12(c) are being met at this time. The Q/A Manager or designee visually inspects and samples eight randomly selected surfaces daily prior to operations. If deficiencies are found on food contact surfaces, the area will be re-cleaned and re-inspected prior to start up. Each area supervisor is responsible for employee hygiene practices, employee and product traffic patterns, sanitary product handling procedures, and cleaning procedures. Monitoring will be conducted once per shift by the QA Manager or designee. The requirements of 9 CFR 416.12(d) are being met at this time. The program also includes the following information: Exposed finished product that fall on the floor will be discarded. RTE product dropped prior to slicing or dicing must not be used and non-RTE product dropped before the CCPs can be used after it is washed off.

GS6 **Does the plant have an extended cleanup (less than daily) written in the SSOP?**

_____ Yes
___X___ No

GS6a **If yes, does the design of the procedure support extended cleanup?**

_____ Yes
___X___ No

GS6b **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The written sanitation procedures were reviewed and observations indicate all product contact surfaces are cleaned prior to the start of operations with the exception of the smokehouse carts, sticks, product peeling tables, and formulation tubs holding product. These items are emptied during production and then cleaned prior to reuse. The cleaning of these items are documented by the employee conducting the task. These records were reviewed and adequately document the cleaning.

GS7 **Are all sanitation procedures conducted incorporated into the SSOP?**

_____ Yes
___X___ No

GS7a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The Standard Sanitation Operating Procedures program was reviewed and implementation of some pre-operational and operational procedures was observed. Pre-operational procedures are identified as such and indicate cleaning and sanitizing of all product contact surfaces of equipment and utensils will be conducted prior to the start of production. However, some equipment is not available for cleaning prior to production and is not addressed in the written program. (i.e. smokehouse carts, sticks, product peeling tables, and formulation tubs. The cleaning of these items is documented by the employee conducting the task and were reviewed. NR# was issued for failure to meet the requirements of 9 CFR 416.12(a). All other SSOPs observed are included in the written program and indicate the program adequately describes sanitary procedures conducted before and during production to ensure; sanitary conditions are established and maintained.

GS8 **Does the plant monitor the implementation of SSOP procedures no less than daily as required under 9 CFR 416.13(c)?**

___X___ Yes
_____ No

GS8a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision in GS8.** The written SSOP programs were reviewed and indicate monitoring will occur daily prior to production and once each production shift during operations. The company is monitoring and documenting the implementation of the SSOPs. The requirements of 9 CFR 416.13(c) are being met at this time.

GS9 **Has the establishment maintained daily SSOP records as required?**

_____ Yes
___X___ No

GS9a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The following records associated with the SSOP program were reviewed 11/1/2011 through 12/31/2011: Form A Pre-Operational Sanitation Inspection Form, Form B SSOP Monitoring Form, Contact (RODAC) Plates, Form B Deviation Report, and Visual Inspection Pre-Operational Form. Pre-operational deficiencies identified included re-washing, re-inspecting, and sanitizing of the affected area. Records reviewed indicate the establishment is maintaining documents to adequately demonstrate the implementation and monitoring of the SSOP's. However, when operational deficiencies are found, incomplete corrective actions are documented on Form B Deviation Report. Deficiencies were identified however, product disposition was not included. This finding was discussed with Jim Whitham. He stated that the product was cooked per the Alternative Corrective Action program, which states the product, will be cooked to 160°F for 5 minutes. These records were provided for review and contained the necessary information to indicate the Alternative Corrective Actions were implemented. The

SSOP records do not adequately document product disposition as required thus not meeting the requirements of 9 CFR 416.16(a) NR# was issued for this finding.

GS10 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 416.15(a)?

___X___Yes
_____No
_____No deficiencies in the last 60 days

GS10a If yes, were all applicable parts of 9 CFR 416.15 (b) met?

___X___ Yes
_____No

GS10b Why did you come to this conclusion? Briefly describe the corrective actions taken and discuss any noncompliance. Describe the observations and/or documents used to reach your decisions in GS10 and GS10a. When operational deficiencies are found, incomplete corrective actions are documented on Form B Deviation Report. The following deficiencies were identified however, product disposition was not included. This finding was discussed with Jim Whitham. He stated that the product was cooked per the Alternative Corrective Action program, which states the product, will be cooked to 160°F for 5 minutes. These records were provided for review and contained the necessary information to indicate the Alternative Corrective Actions were implemented as required by 9 CFR 416.15(b). The SSOP records do not adequately document product disposition as required thus not meeting the requirements of 9 CFR 416.16(a) NR# was issued for this finding.

GS11 Does the establishment conduct microbiological testing as part of the SSOP? (The questions GS11-18 are not exactly regulatory but they are options a plant may choose to use to address sanitation issues. The Agency needs to know if plants utilize these controls in order to separate plants that are just meeting the regulations from plants that create additional controls to ensure sanitation. This information may also be valuable for the EIAO in assessing the plant's food safety system.)

___X___ Yes
_____No

GS11a If yes, what organism(s)? Check all that apply

_____Generic E. coli
_____Coliform
_____Enterobacteriaceae
___X___APC
_____ATP luminescence
_____Other

GS11a1 Please specify. Replicate Organisms Detection and Counting Plates (RODAC®): Eight randomly selected locations are sampled each production day by touching the RODAC plate directly on the identified surface. The plates are then incubated for 48 hours at 35°C. The company allows 10 CFU or less, results exceeding 10 CFU would prompt re-sampling of that area the following

week. Results reviewed indicate results are routinely within the established limit. On two occasions in the last 60 days, limits were exceeded. Actions include intensified cleaning and re-sampling.

GS11b Is the procedure designed to find the organisms of concern?

___X___ Yes
_____ No

GS11c Does the plant use the data in decision making?

___X___ Yes
_____ No

GS11d Why did you come to these conclusions? Describe the observations and/or documents used to reach your decisions in GS11, GS11a - c. Replicate Organisms Detection and Counting Plates (RODAC®) are not intended to identify any specific organism only general aerobic bacterial loads on the surface sampled. The company allows 10 CFU or less, results exceeding 10 CFU would prompt re-sampling of that area the following week. Results reviewed indicate results are routinely within the established limit. On two occasions in the last 60 days, limits were exceeded. Actions include intensified cleaning and re-sampling.

GS12 Are employee hygiene procedures available in a written document?

___X___ Yes
_____ No

GS13 Are employees trained in hygiene procedures?

___X___ Yes
_____ No

Gs13a Describe the training procedures, observations and/or documents used to reach your decision and discuss whether they are adequate to prevent direct product contamination. Are they available in multiple languages? The company includes employee hygiene as part of the new employee training which is conveyed via video. Each employee completes a test to demonstrate the knowledge of the information and training documents are maintained. Training is available in both English and Spanish.

GS14 Are outer garments removed when leaving work area?

___X___ Yes
_____ No

GS15 Are gloves used properly?

___X___ Yes
_____ No

GS15a **Describe how you came to the conclusion in GS15.** Employees observed during operations were wearing gloves in the production areas and removing frocks when leaving the production areas as stated in the written program.

GS16 **Do the employees use a 20-second hand wash (or comparable method of sanitizing) before starting and returning to work?**

___X___ Yes
_____ No

GS17 **Are food and operator hand tools (knives/food contact utensils) stored in a sanitary manner?**

___X___ Yes
_____ No

GS18 **Does the establishment rotate sanitizers?**

___X___ Yes
_____ No

GS18a **If yes to GS18, describe the rotation procedure.** In discussion with Jim Whitham, QA Manager it was indicated that quaternary ammonia is used daily and a chlorine-based sanitizer is used on the weekends.

GS18b **Why did you come to these conclusions? Describe the observations and/or documents used to reach the decision. Describe any findings during review of the SSOP records.** In discussion with Jim Whitham, QA Manager it was indicated that quaternary ammonia is used daily and a chlorine-based sanitizer is used on the weekends.

GS19 **Describe any sanitation findings not addressed in any of the previous questions.** All findings were previously discussed.

GS20 **Analysis and Summary: Briefly describe the SPS/SSOP program design and any concerns and/or non-compliances found by summarizing your analysis of the above gathered data related to your sanitation findings. Also, include positive findings.** During the Comprehensive Food Safety Assessment, the written sanitation program, SSOP documentation, and program implementation was reviewed. The development and implementation of the company's SSOPs, SOP, GMPs, and other pre-requisite programs are intended to meet the requirements of 9 CFR 416. Noncompliance with the requirements of 9 CFR 416.1-416.4 was not observed.

Liguria Foods has developed written programs that contain procedures to be conducted daily to ensure sanitary conditions are established and maintained with the following exceptions: some equipment is not available for cleaning prior to production and is not addressed in the written program including smokehouse carts, sticks, product peeling tables, and formulation tubs however, records were provided documenting the cleaning. NR# was issued for failure to meet the requirements of 9 CFR 416.12(a).

Implementation of the sanitation procedures and sanitary conditions of the plant were observed prior to and during operations. No insanitary conditions were observed. The company conducts sampling to demonstrate that sanitary conditions are maintained in the facility. RODAC results were reviewed and were below the established limit. Pre-operational monitoring was observed, equipment was disassembled for cleaning and inspected as stated in their written program, the areas were cleaned and sanitized prior to operating.

Records reviewed indicate the establishment is maintaining adequate documentation to demonstrate the implementation, monitoring, and corrective actions taken in regards to the SSOP's with the following exception: Operational deficiencies records include incomplete corrective actions, product disposition was not included. This finding was discussed with Jim Whitham. He stated that the product was cooked per the Alternative Corrective Action program, which states the product, will be cooked to 160°F for 5 minutes. These records were provided for review and contained the necessary information to indicate the Alternative Corrective Actions were implemented. The SSOP records do not adequately document product disposition as required thus not meeting the requirements of 9 CFR 416.16(a) NR# was issued for this finding.

Based information gathered during review of the written programs and associated records as well as observations during the CFSA, the company has developed written programs and or maintained records adequate to address sanitary conditions at the facility. The non-compliance identified indicates clarification is needed in the written program and complete corrective action documentation is necessary. Other supporting documents were provided sufficient to conclude there is not a food safety concern with these findings.

General Food Defense Plan

G1 The plant states that they do have a written food defense plan but they are unwilling to share it with FSIS.

_____ Yes

___X___ No

G1a If plant was unwilling to share their food defense plan with FSIS please describe their reasons. The company did provide their food defense program for review.

G2 In a table format: List all of the establishment's food defense plans. Liguria Food Defense Plan

G3 In a table format: Briefly discuss any reporting associated with inadequate food defense findings, non-routine incident reporting (NRIRs), 08S procedures, Memorandum of Inspections (MOI), deliberate contamination of FSIS regulated product, repetitive vulnerability reports or procedures, or suspicious activities observed by program personnel while performing their normal duties. There have been no food defense concerns reported.

OS1 Does the establishment have food defense measures in place for the exterior of the building?

___X___ Yes

_____ No

OS1a Describe the measures in place for the exterior of the building.

The company has a fence around the perimeter of the facility with a manned gate where vehicles enter.

OS2 Are the following exterior opening secured with locks, seals, or sensors when unattended (after hours/weekends) to
prevent entry by unauthorized persons?

___X___ Outside doors and gates
_____ Windows
_____ Roof Openings
_____ Vent Openings
_____ Trailer (truck) bodies
_____ Tanker truck hatches
_____ Railcars
_____ Bulk storage tanks/silos
_____ Other

OS2a Please specify.

Insert Text

OS3 Does the establishment have food defense procedures for people and/or vehicles entering the plant and/or parking in the lot?

___X___ Yes

_____ No

OS3a Does the property have a controlled or guarded entrance?

___X___ Yes

_____ No

OS3b Are employee vehicles identified using placards, decals, or some other form of visual identification?

_____ Yes

___X___ No

OS3c Are authorized visitor/guest vehicles identified using placards, decals, or some other form of visual identification?

_____ Yes

___X___ No

OS3d Why did you come to these conclusions? Describe the observations and/or documents that provide support for the answers chosen for all OS3 questions. The perimeter of the facility is fenced. Employees enter through a controlled gate and vehicles entering the grounds must do so through a guarded gate. Employee vehicles observed were not identified via placard or any other identifier.

GIS1 Does the establishment have food defense measures for inside security?

___X___ Yes

_____ No

GIS1a Why did you come to this conclusion? Describe the procedures and any observations and/or documents used to reach the conclusion in GIS1. Visitors must enter through the front office and must sign in. Plant management and area supervisors are responsible for interior security.

GIS2 Are the controls for the following systems restricted (e.g., by locked door/gate or limiting access to designated employees to prevent access by unauthorized persons? (Helpful information is provided at the following website: www.cdc.gov/niosh/bldvent/2002139.html. If yes, check all that apply.

___X___ Heating, Ventilation, and Air conditioning systems
___X___ Propane gas, compressed gases, or heating oils
___X___ Water systems

___X___ Electricity
_____ Disinfection systems
_____ Clean-in-place (CIP) systems or other centralized chemical systems
_____ Other

BIS2a Please specify.

Insert Text

GIS3 Does the establishment have food defense procedures in place for its in-plant laboratory facilities, equipment, and operations?
___X___ Yes
_____ No

GIA3a If yes, describe the procedures in place for its in-plant laboratory. Access to the lab is restricted to authorized personnel only.

PS1 Does the establishment have food defense procedures in place for its processing operations?
___X___ Yes
_____ No

PS1a Why did you come to this conclusion? Describe the procedure and any observations and/or documents used to reach the decision. Production areas are restricted to plant employees and regulatory officials. Visitors are accompanied by plant management at all times. Area supervisors are responsible for inspecting the area and equipment for security concerns.

SS1 Does the establishment have food defense procedures in place for its storage areas?
___X___ Yes
_____ No

SS1a Why did you come to this conclusion? Describe the procedure and any observations and/or documents used to reach the decision. Storage areas are observed during sanitation monitoring.

SRS1 Does the establishment have food defense procedures in place for its shipping and receiving operations? (Helpful information is provided at the following website: http://www.fsis.usda.gov/oa/topics/transportguide.htm)
_____ No
___X___ Yes

SRS1a Why did you come to this conclusion? Describe the observations and/or documents used to reach this decision. If yes, briefly discuss the establishment's food defense procedures for shipping and receiving operations. Shipping and receiving vessels are observed during loading and unloading. Items received into the facility are compared to the BOL and inspected during the unloading process.

WIS1 Does the establishment have food defense procedures in place for its water and ice supply?

(Helpful information is provided at the following website:
http://www.epa.gov/region1/eco/drinkwater/pdfs/drinkingH2Ofactsheet.pdf)

___X___ Yes

_____ No

WIS1a Why did you come to this conclusion? Describe the procedures and any observations and/or documents used to reach the decision. Water is supplied by the City of Humboldt and is tested in-house monthly for coliforms and pH. Ice is not used in this facility.

MH1 Briefly discuss the establishment's food defense procedures to ensure mail-handling security. Mail is handled in the front office of the facility away from the production areas.

PES1 Does the establishment have food defense procedures in place for ensuring that personnel adhere to the security requirements?

___X___ Yes

_____ No

PES1a Why did you come to this conclusion? Describe the procedures and any observations and/or documents used to reach the decision. Employees are required to enter through a secured entrance. Employee assigned lockers are inspected randomly.

ITI In a table format: Briefly describe how the establishment implements, manages, and updates the food defense plan, to include periodical review, emergency contact information, periodic testing (drills, tabletop exercises, mock incidents and recalls, post-event evaluation and lessons learned, evacuation procedures, and continuity of operations plans (COOP). Food security audits are performed on a regular basis, the last being in December 2011. Mock product recalls are conducted and procedures have been adequate.

Demographics, Recommendation, and Background

Version Type: Working Version #: 3

Demographics and Recommendation

DR1 Establishment Demographics
Liguria Foods, Inc.
1515 N 15th St
Humboldt, IA 50548

DR2 Reason for visit
Routine Assessment - 4-year cycle

DR2a Sampling performed as part of FSA.

_____RLM
_____ IVT
_____ IIT

DR2b Please describe IIT sampling plan and indicate organism analyzed, number of samples collected, method of sample collection, and product type sampled. No sampling was conducted.

DR3 Recommendations

_____ No Action
_____ 30 Day Reassessment Letter
___X___ NRs written by in-plant inspection
_____ NOIE
_____ Suspension/Withdrawal

DR4 FSA Executive Summary Supporting Recommendation (350 words or less)
Liguria Foods, Inc. is a small facility (in HACCP terms) that produces ready to eat (RTE) fermented meat products. Raw beef and pork products are come into the facility and ground for use in product that is fermented, heated, and dried. All Products are Consumer ready and have a Shelf life of 9 months at >40°F; indefinite if refrigerated or frozen. No allergens are used in products currently produced at this facility.

Documents reviewed, indicate a hazard analysis was conducted to determine the food safety hazards reasonably likely and not reasonably likely to occur in their process. The Shelf Stable Dry Sausage HACCP Plan identifies all hazards reasonably likely to occur and sufficient controls are in place.

Review of the HACCP plan and associated supporting documents indicate the HACCP plan has been adequately developed with the following exceptions; The HACCP plan does not include direct observation of corrective actions. Also the written program states: "reviews will be considered to be successful if a NR/deviation report is not filled out". The HACCP records do not include results as required. A NR was issued for failure to meet 9 CFR 417.2(c)(7) and 9 CFR 417.5(a)(3).

The company conducts raw and finished product as well as environmental testing demonstrating adequate cleaning and bacterial control. The process is supported by scientific documentation as

well as in-house validation of the process.

Liguria Foods has addressed the Sanitation Performance Standards (SPS) and SSOP requirements through the development and implementation of SSOPs and GMPs. The sanitation programs have been designed to address the cleaning and sanitizing of FCS and non-FCS. However, some equipment is not available for cleaning prior to production and is not addressed in the written program. (i.e. smokehouse carts, sticks, product peeling tables, and formulation tubs). Upon further investigation, it was determined that the cleaning of these items is documented by the employee conducting the task. A NR record was issued for failure to meet the requirements of 9 CFR 416.12(a). No other noncompliance with the SPS or SSOP requirements were identified and all parts of §416 are currently being met.

The noncompliance observed do not result in food safety concerns based on observation that adequate procedures are being implemented. Based on all information reviewed the company has developed an adequate food safety system sufficient to produce safe and wholesome product supporting the recommendation that noncompliance found be addressed with a NR.

DR5 Describe any NRs written as part of the FSA. One HACCP recordkeeping NR was issued for failure to meet 9 CFR 417.2(c)(7) and 9 CFR 417.5(a)(3) and one SSOP recordkeeping NR was issued for failure to meet the requirements of 9 CFR 416.12(a).

DR6 Please copy and paste in any MOIs written as part of the FSA. None

DR7 Describe the entrance conference. On January 9 2012, EIAO, Aubrey Williams arrived at establishment 15747 M. At that time, a brief meeting was held with relief inspector, to discuss any concerns, review the assessment methodology, and answer any questions relative to the assessment. At approximately 1000, an entrance meeting was conducted. The assessment processes as well as possible outcomes of the assessment were explained including the Rules of Practice (9 CFR 500). They were informed that if they elect to make changes, based on findings, during the course of the FSA that they are free to do so however, NRs, and/or overall outcomes would be based on initial findings. They were given an opportunity to ask questions and had no questions at that time. Those in attendance for Liguria Foods included Jim Whitham, HACCP Manager. FSIS attendees included: Aubrey Williams, EIAO, and Inspector, Oscar Eilerts. The company had no further comments or questions at that time. The entrance meeting was concluded.

DR8 Describe the exit conference. On Feburary 2, 2012 an Exit Meeting was conducted at Establishment 15747 M. Those in attendance for Liguria Foods included Jim Whitham, HACCP Manager. FSIS attendees included: Aubrey Williams, EIAO, and Inspector, Oscar Eilerts. The company had no further comments or questions at that time. The entrance meeting was concluded.

DR9 List any reference source materials given to the plant during the FSA. None

Background Inspection Information

BIF1 List of NRs written by in plant FSIS personnel during the last 6 months of operation.
NRs generated from 06/01/2011 through 01/04/2012:

Date: 9/12/2011 NR #:2-2011 ProcCode:01C02 Regs: 416.2(d), 416.13(c)

Condensation was observed in the raw grinding department

Date: 9/14/2011 NR #: 3-2011 ProcCode: 01C01 Regs: 416.16(a)
On 9/12/2011, FSIS inspection program personnel (IPP) documented a SSOP plan noncompliance pertaining to beaded condensation. The Operational SSOP record(s) Form B dated 9/12/2011 did not include FSIS inspection findings and corrective action documentation.

BIF2 **Briefly discuss any preliminary food safety system implementation and/or design issues demonstrated by the NRs listed above.** NRs generated from 06/01/2011 through 01/04/2012 were reviewed. The two NRs issued during that time were related to one incident. The information reviewed did not imply an issue with the food safety system.

BIF3 **Briefly discuss how the above identified food safety implementation and/or design issues impact public health and the establishment's ability to produce unadulterated product.** NRs generated from 06/01/2011 through 01/04/2012 were reviewed. The two NRs issued during that time were related to one incident. The information reviewed did not imply an issue with the food safety system.

BIF4 FSIS Sample History

Collect Date	Form Number	Product Type	Product Name	Tested For	Test Result
8/16/2011	11577677	Product-RTE-Acidified/Fermented	Link Pepperoni	Listeria monocytogenes -/+	Negative
8/16/2011	11577677	Product-RTE-Acidified/Fermented	Link Pepperoni	Salmonellae -/+	Negative

BIF5 **Briefly discuss any preliminary food safety system implementation and/or design issues demonstrated by any positive samples listed above.** No preliminary food safety system implementation and/or design issues are demonstrated by the sampling results listed above.

BIF6 **Briefly discuss how the above identified food safety implementation and/or design issues impact public health and the establishment's ability to produce unadulterated product.** No preliminary food safety system implementation and/or design issues are demonstrated by the sampling results listed above which may impact public health and the establishment's ability to produce unadulterated product.

BIF7 **Has the establishment had a consumer complaint in the past 6 months?**

_____ Yes
___X___ No

BIF7a **Describe any consumer complaints found over the last 6 months.** Data contained in the Consumer Complaint Monitoring System was reviewed. There were no consumer complaints documented in the last 12 months.

General

G1 List all HACCP 03F plans, products produced using those plans, CCPs, critical limits, monitoring procedures, and verification procedures associated with those plans using the template provided.

HACCP Plan	Products Produced	CCP	CL	Monitoring Procedures	Verification Procedures
Heat Treated Shelf Stable - Pre-Heat Treated Pepperoni, Genoa, and Hard Salami (Signed by Jim Whitham on 12/14/2011)	Pepperoni, Genoa, and Hard Salami (sliced, diced, or whole)	Progress of the Fermentation CCP-B1 (*Staphylococcus aureus*)	pH ≤5.0	A pH will be monitored by Laboratory personnel or designee and measured in a 1/10 solution of deionized water or an equivalent and recorded in the pH book.	Supervision or their designee will review pHs on the below stated basis. RR: daily or next production day. DO: min monthly. CM: min of weekly. (reviews will be considered to be successful if a NR/deviation report is not filled out also see instructions bottom of pH page for successful completion)
		Post Heat Treating CCP-B2	Internal Temperature 135°F for 15 min. or 128°F for 60 min.	Smoke house operator will use a calibrated probe placed in the geometric center of one piece of product in each house	QA Process Foreman or their designee will verify smokehouse charts on the below stated basis. RR: daily or next production day. DO: min of quarterly. CM: min of

					monthly. (reviews will be considered to be successful if a NR/deviation report is not filled out)

G2 **If corrective actions have been taken by the plant, were those corrective actions effective?**

_____ Yes
_____ No
___X___ No corrective actions needed in the past 12 months

G2a **How many times within the last 12 months did the establishment have deviations from CCPs?**

___X___ 0 times
_____ 1-2 times
_____ 3-5 times
_____ >5 times

G2b **For G2 and G2a, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.** Deviation reports generated from January 2010 through December 2011 were reviewed. There were no CCP deviations documented.

G3 **Was the establishment given any enforcement action within the last 12 months?**

_____ Yes
___X___ No

G3a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.** FSIS data was reviewed; there were no enforcement actions associated with this establishment in the last 12 months.

G3b **If yes, what type of enforcement action was taken?**

_____ Notice of Intended Enforcement (NOIE)
_____ 30-day letter
_____ Notice of Suspension

G3c **If yes, what was the reason for the enforcement action?**

_____ Sanitation deviation
_____ Listeria rule deviation
_____ Positive Listeria monocytogenes sample

_____ Positive Salmonella sample
_____ Positive Escherichia coli O157:H7 sample
_____ Other

G3d **Please specify.** FSIS data was reviewed; there were no enforcement actions associated with this establishment in the last 12 months.

G3e **For G3c and G3d, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.** FSIS data was reviewed; there were no enforcement actions associated with this establishment in the last 12 months.

G4 **Has the establishment recalled product in the last 12 months?**

_____ Yes
___X___ No

G4a **If yes, what was the reason for the recall?**

_____ Positive Listeria monocytogenes sample
_____ Positive Salmonella sample
_____ Positive Escherichia coli O157:H7 sample
_____ Under processing
_____ Undeclared allergen
_____ Extraneous material
_____ Mislabeling
_____ Other

G4b **Please specify.**

G5 **Does the establishment accepts returned product?**

___X___ Yes
_____ No

G5a **Describe how the establishment utilizes returned product.** Per the Rejected and Returned Product Policy, product rejected at a customer's facility should be returned to the distribution center or producing facility, kept refrigerated or frozen, and cannot be resold without the plant manager's approval. Any product with damaged packaging will be considered inedible. Repacking may occur with approval from the Quality Assurance Manager.

G6 **Does the establishment rework product?**

___X___ Yes
_____ No

G6a **Describe how the establishment controls the use of rework product.** Per the Rework Control program, rework is defined as any product that is not First Pass. Product intended to be reworked is

labeled with the date, line, period of original production, formula number, and use by date. The weight of product reworked will be included on the Blender Batch Sheet.

G7 **Does the establishment produce products that contain allergens as well as products that do not contain allergens?**

_____ Yes

___X___ No

G7a **If yes, describe the procedures the establishment has incorporated into their food safety system to ensure allergen containing ingredients and residue from product containing allergens does not contaminate products that are not intended to contain allergens? Examples could include ingredient storage, product formulation, labeling, process scheduling, sanitation, etc.** No allergens are used in products currently produced at this facility.

G7b **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision in G7 and G7a.** Product ingredients and labels were reviewed. Products currently produced at this facility do not contain allergens.

G7c **Has the establishment initiated a recall due to an undeclared allergen in the last 12 months?**

_____ Yes

___X___ No

G7c1 **If yes, what corrective actions did the establishment take in response to the recall?** Product ingredients and labels were reviewed. Products currently produced at this facility do not contain allergens.

G8 **Does the establishment add non-meat ingredients to any RTE products after the final lethality step (examples may include sauces, spices, glazes. etc.)?**

_____ Yes

___X___ No

G8a **Please describe the products and added non-meat ingredients.** The addition of non-meat ingredients take place prior to the fermentation and heating process.

G8b **Does the establishment have adequate support in their hazard analysis addressing these non-meat ingredients added to RTE meat and poultry products after the final lethality step?**

_____ Yes

___X___ No

G8c **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision in G8 -G8b.** The flow diagram was reviewed and production practices were observed which indicate the addition of non-meat ingredients takes place prior to the fermentation and

heating process.

G9 **Does the establishment keep meat and poultry raw materials at or below 40° F during receipt and storage?**

_____ Yes
__X__ No

G9a **If no, at what temperature are raw materials stored?** Per the Raw Material Receiving Policy, fresh meat must be ≤45°F upon receipt. Product storage area temperatures are monitored. Records reviewed indicate temperatures are maintained ≤45°F.

G9b **If the establishment keeps the raw materials at or below 40°F for more than a week, are they frozen?**

_____ Yes
__X__ No

G10 **Does the establishment use degree-hours as described in the AMIF guidelines to control Staphylococcus aureus?**

__X__ Yes
_____ No

General Hazard Analysis, Flow Diagram and HACCP

H1 **Based on your scientific knowledge of the process information in the Hazards Guide, Agency guidance documents, and the establishment's supporting documentation, did the establishment consider all appropriate hazards and determine those hazards that are reasonably likely to occur?**

__X__ No
_____ Yes

H2 **Are all decisions made in the hazard analysis supported with documentation on file?**

__X__ Yes
_____ No

H3 **Why did you come to the conclusions in H1 and H2? Briefly explain how the answers in H1 and H2 were determined by describing the hazards considered by the establishment and their thought process in determining those reasonably likely to occur. Include the names of documents and cite any non-compliance.** A hazard analysis was conducted however all potential hazards were not included.

Hazards identified as not reasonably likely to occur include; foreign material, Listeria, and chemical contamination. Metal detection and sanitation procedures are in place to control the likelihood of physical and chemical contaminants. Historical data supports that the controls are adequately controlling the hazards as intended. The company has a Listeria control program in place to address environmental conditions and further supports the decision that it is not likely to occur in the process due to the growth parameters being exceeded by the characteristics of the finished products (water activity and pH).

Staphylococcus aureus growth and Enterotoxin development can occur during fermentation and is appropriately identified as reasonably likely to occur in the process. Records reviewed indicate the company is achieving a pH of ≤5.0 prior to increasing the heat and within the degree hours outlined in there supporting document. Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products, The American Meat Institute Foundation, October 1997. Finished product testing for *Staphylococcus* Enterotoxin is also conducted, all results reviewed were negative.

Raw pork and beef products are received into the facility. Cattle and swine are known carriers of *Trichinella spiralis, Salmonella, and Escherichia coli* O157:H7 are biological hazards potentially present on incoming raw meat. and are appropriately identified as likely to occur in the process. Outgrowth of pathogens is controlled via temperature controls in the production and storage areas. The company has implemented adequate controls to reduce the likelihood of pathogen survival after fermentation and thermal processing. The company has both scientific support as well as process validation studies on file. Scientific documentation supporting the critical limits are as follows: Validation of pepperoni processes for control of *Escherichia coli* O157:H7. *Journal of Food Protection* 59(12): 1260-1266. Good Manufacturing Practices. *AMIF October 1997.* Ingham, S.C., D.R. Buege, B.K. Dropp, and J.A. Losinski. 2004. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of *Escherichia coli* O157:H7 and *Salmonella* during Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation (110°F up to 15.3 hours and heat treatment 139.5°F) is adequate to achieve a pH of ≤5.3 and a 6-log reduction in *E. coli* and *Salmonella*. Records reviewed indicate the product consistently meets the parameters. Trichinella is controlled via processing parameters required by 9 CFR 318.10.

H4 **Does the plant use a prerequisite program(s)?**

_____ No

__X__ Yes

H4a **If yes to H4, list the names of all the prerequisite programs used as part of the HACCP category and briefly describe the hazards each prerequisite program is preventing along with the monitoring procedures and records generated.**

Program Title	Hazard Controlled	Monitoring Procedure	Records
SSOP	Cross contamination	Daily monitoring of pre-operational and operational sanitation	Form A Pre-Operational Sanitation Inspection Form, Form B SSOP

		8 surface samples collected daily and analyzed for total plate count	Monitoring Form, Contact (RODAC) Plates, Form B Deviation Report, and Visual Inspection Pre-Operational Form
Room temperature monitoring (no written program)	Pathogen growth	Room temperatures are monitored daily	Room Temps
Metal Detection	Foreign material	Metal detector functionality checks daily with ferrous, non-ferrous, and stainless	Metal Detection Check Sheet
Rejected and Returned Product	Contamination	Returned loads are evaluated for disposition	Returned Product Sheets

H4b **Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur?**

_____ Yes
___X___ No

H4c **Why did you come to this conclusion? Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may affect the production of safe product. Cite any non-compliance.** Pre-requisite programs and supporting documents, as well as associated records generated from November 1, 2011 through December 31, 2011 were reviewed. There were no programs lacking adequate support. The records indicate the programs are being implemented and monitored.

H4d **If yes to H4, with the records reviewed, has the plant had a deviation from compliance with a prerequisite program?**

___X___ No
_____ Yes

H4e **If yes to H4d, did it constitute a trend, and did the plant reassess?**

_____ Yes
___X___ No

H4f **Is the establishment monitoring and keeping adequate records for each of the prerequisite programs?**

_____ No

___X___ Yes

H4g **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision and cite any non-compliance.** Pre-requisite programs and supporting documents, as well as associated records generated from November 1, 2011 through December 31, 2011 were reviewed. There were no deviations noted during that time frame. The records indicate the programs are being implemented and monitored.

H4h **Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.** Based on information reviewed, the current pre-requisite programs in place are appropriately developed and adequately implemented to support decisions made in the HACCP plan.

H5 **Are all steps in the process(s) included in the flow diagram?**

___X___ Yes
_____ No

H6 **Briefly discuss any regulatory noncompliance associated with the flow diagram.** The hazard analysis and flow diagram were reviewed and product flow through the facility was observed. The steps identified on the flow diagram mirror the steps in the hazard analysis and adequately depict product flow through the process.

H7 **Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s) by identifying a point in the process that will prevent eliminate, or reduce to acceptable levels for each?** The HACCP plan was reviewed and addresses each of the hazards identified as reasonably likely to occur (RLTO) in the hazard analysis. The presence, growth, and survival of pathogens are hazards RLTO and the company has indentified two locations in the process where measures are employed to control the hazards; fermentation and heat treatment.

H7a **Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. Cite any non-compliance.** All hazards are adequately addressed.

H8 **Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits**

___X___ No
_____ Yes

H8a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The HTSS HACCP plan was reviewed and indicates the following procedures and frequencies will be used when monitoring the CCPs: CCP B1, pH will be monitored by Laboratory personnel or designee and measured in a 1/10 solution of deionized water or an equivalent and recorded in the pH book. CCP B2, The Smokehouse operator will use a calibrated probe placed in the geometric center of one piece of

product in each house.

H9 **Are the monitoring procedures being performed as described in the HACCP plan?**

___X___ Yes

_____ No

H10 **Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan?**

___X___ Yes

_____ No

H11 **For H9 and H10, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.**

Monitoring of the pH and temperature CCPs was observed. Each of the procedures were observed being conducted as described in the written program. The CCP B1 and CCP B2 HACCP Sheet were reviewed and indicate monitoring procedures are being performed at the frequencies specified in the written program.

H12 **Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?**

_____ No

___X___ Yes

H13 **Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?**

_____ Yes

___X___ No

H14 **Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?**

___X___ Yes

_____ No

H15 **For H12-H14, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The HTSS HACCP plan was reviewed and contains the frequency for calibration of the monitoring devices, direct observation of monitoring, and record review. The company also maintains detailed calibration procedures for each of the instruments used to monitor the CCPs. The HACCP plan does not include direct observation of corrective actions. A noncompliance with 9 CFR 417.2(c)(7) exists and will be on

NR #.

H16 **Does the HACCP plan list product sampling as a verification activity?**

___X___ No

_____ Yes

H16a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.** The HTSS HACCP plan was reviewed and did not include product sampling as a verification activity.

H17 **Are process-monitoring instrument calibration activities conducted as per the HACCP plan?**

___X___ Yes

_____ No

H18 **Are direct observation verification activities conducted as per the HACCP plan?**

___X___ Yes

_____ No

H19 **Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?**

___X___ Yes

_____ No

H20 **For H17-H19, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.** During the assessment, the accuracy check of the temperature probes and pH meter was observed and conducted as described in the written program. Direct observation and records review activities were not observed however, the HACCP records reviewed indicate the company is performing the activities at the stated frequencies.

H21 **Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?**

___X___ Yes

_____ No

H22 **Does the HACCP plan recordkeeping system provides for documenting actual values and observations obtained during monitoring?**

_____ No

___X___ Yes

H23 For H21 and H22, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance. The HTSS HACCP Plan was reviewed. The following records are maintained to document CCP monitoring for this HACCP plan, CCP B1 and Green pHs The records were reviewed and adequately document monitoring of the CCPs and contain actual values obtained during monitoring as required by 9 CFR 417.2(c)(6).

H24 **Does the establishment have all scientific support documentation for initial validation (first part) on file?**

_____ Yes

___X___ No

H24a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The company has both scientific support as well as process validation studies on file. Scientific documentation supporting the critical limits are as follows: Validation of pepperoni processes for control of *Escherichia coli* O157:H7. *Journal of Food Protection* 59(12): 1260-1266. Good Manufacturing Practices. *AMIF October 1997.* Ingham, S.C., D.R. Buege, B.K. Dropp, and J.A. Losinski. 2004. Survival of *Listeria monocytogenes* during storage of ready-to-eat meat products processed by drying, fermentation, and/or smoking. *Journal of Food Protection*. 67: 2698-2702. Role of Lactic Acid Bacteria (LAB) in Food Preservation and Human Health, *Pakistan Journal of Nutrition.*

A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella during Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation (110°F up to 15.3 hours and heat treatment 139.5°F) is adequate to achieve a pH of ≤5.3 and a 6-log reduction in *E. coli* and *Salmonella*. Records reviewed indicate the product consistently meet the parameters.

H25 **Does the establishment have the decision-making documents associated with the selection of each CCP?**

_____ No

___X___ Yes

H26 **Do the documents explain why the establishment selected that location for the CCP?**

_____ No

___X___ Yes

H27 **H25 and H26, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** A hazard analysis was conducted to identify each step in the process and determine the potential hazards that exist.

The flow diagram identifies and supports the step in the process where adequate control, for said hazards, could be applied.

H28 Does the establishment have scientific, technical, or regulatory support for the critical limit?

_____ No

___X___ Yes

H29 Does the support appear credible?

___X___ Yes

_____ No

H30For H28 and H29, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance. The company has scientific support, process validation studies, as well as plant historical data to support the selection of the critical limits. Trichinella is controlled via processing parameters required by 9 CFR 318.10. Scientific documentation supporting the critical limits are as follows: Validation of pepperoni processes for control of *Escherichia coli* O157:H7. *Journal of Food Protection* 59(12): 1260-1266. Good Manufacturing Practices. *AMIF October 1997.* Role of Lactic Acid Bacteria (LAB) in Food Preservation and Human Health, *Pakistan Journal of Nutrition.* On-going validation includes; raw product testing conducted prior to cooking and finished product testing. *Staphylococcus aureus* growth and Enterotoxin development can occur during fermentation and is appropriately identified as reasonably likely to occur in the process. The company verifies the progression of the fermentation process by taking product pH (CCP) prior to starting the heat treatment. The smokehouses are equipped with a continuous (every 5 minutes) temperature monitoring system. Records from the system where reviewed and indicate the company is achieving a pH of ≤5.0 prior to increasing the heat and within the degree hours outlined in there supporting documents. Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products, The American Meat Institute Foundation, October 1997. Finished product testing for Staphylococcus Enterotoxin is also conducted; all results reviewed were negative, further supporting the effectiveness of the process. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of *Escherichia coli* O157:H7 and *Salmonella* during Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation (110°F up to 15.3 hours and heat treatment 139.5°F) is adequate to achieve a pH of ≤5.3 and a 6-log reduction in *E. coli* and *Salmonella*. Records reviewed indicate the product consistently meet the parameters.

H31 Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?

_____ No

___X___ Yes

H32 Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?

_____ No
__X__ Yes

H33 **If the establishment has supporting documents for these decisions, does the documentation support the decisions?**

__X__ Yes
_____ No

H34 **For H31-H33, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The monitoring and verification procedures and frequencies are supported by historical records demonstrating consistently in meeting the critical limits and acceptable verification results. Jim Whitham also maintains a comprehensive database containing water actives, CCP monitoring results and various other information pertaining to production to support current activities.

H35 **Do the records document the monitoring of CCPs and their critical limits?**

__X__ Yes
_____ No

H36 **Do the records include actual temperatures, times, concentrations or other quantifiable values, as prescribed in the establishment's HACCP plan?**

_____ No
__X__ Yes

H37 **Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, or a means by which the records can be associated with a specific production, along with the date and time the record was made?**

_____ No
__X__ Yes

H38 **Are the verification procedures and results of those procedures documented including time and date record was made?**

__X__ No
_____ Yes

H39 **Are the process-monitoring calibration procedures and results being recorded?**

_____ No
__X__ Yes

H40 **Was each entry on the record made at the time the event occurred?**

_____ No

__X__ Yes

H41 **Was each entry on the monitoring, verification, and corrective action records signed or initialed by the establishment employee making the entry?**

__X__ Yes

_____ No

H42 **For H35-H41, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The HTSS HACCP Plan was reviewed. The following records are maintained to document CCP monitoring for this HACCP plan, CCP B1 and Green pHs. The records were reviewed and adequately document monitoring of the CCPs. Each entry contains actual values obtained during monitoring to demonstrate the critical limits are being met. Each entry includes the time and initials of the person conducting the procedure as well as information to identify the production lot. Calibration results are being documented adequately as well. The following record keeping noncompliances with the requirements of 9 CFR 417.5(a)(3) was identified: the written program states: "reviews will be considered to be successful if a NR/deviation report is not filled out". The HACCP records do not include results as required.

H43 **Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products?**

_____ No

__X__ Yes

H44 **Are the records kept on-site for 6 months?**

_____ No

__X__ Yes

H45 **If the records are stored off-site after 6 months, can they be retrieved in 24 hours?**

_____ Yes

_____ No

__X__ Establishment does not store any records off-site

H46 **For H43-H45, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** Records generated in 2009 were reviewed. In discussion with Jim Whitham, it was determined that records are stored off-site.

H47 **Has the establishment reviewed the records associated with the production of the product, prior**

to shipment?

_____ No
__X__ Yes

H47a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The following HACCP records generated from November 1, 2011 through December 31, 2011; CCP B1 and Green pHs. Each record includes a signature date and time signifying a record review had been conducted.

H48 **Does the establishment list corrective actions in its HACCP plan that meet the requirements of 417.3?**

_____ No
__X__ Yes

H49 **Is a responsible party assigned to perform corrective actions?**

_____ No
__X__ Yes

H50 **If corrective actions have been taken by the plant, were those corrective actions effective? If no corrective actions in the past 60 production days, verify the last time the establishment took corrective actions.**

_____ No
__X__ Yes

H51 **How many times within the last 60 days did the establishment have deviations from CCPs?**

__X__ 0 times
_____ 1-2 times
_____ 3-5 times
_____ >5 times

H52 **For H48-H51, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** The HACCP plan contains a statement that all parts of 417.3 will be addressed as well as specific corrective actions for each CCP: B1, "If there is a deviation in the pH the reason will be ascertained by the area foreman and/or Q.C. Mgr. Pending the outcome of the above result the product fermentation may be continued or the product may be reworked, or placed in the inedible container." B2, "The area foreman will ascertain the reason for product not reaching temperature. The product temp./time data must be able to demonstrate a five log kill calc. from F values for *E. coli* O157:H7 or may be reheat treated or alternatively processed by any validated method." Records generated November 1, 2011 through December 31, 2011 were reviewed and indicate no deviations from the critical limits occurred during that time. Deviation reports generated

from January 2011 through December 2011 were reviewed. There were no CCP deviations documented. No corrective actions associated with a CCP deviation were taken in the last 12 months therefore not evaluated during the assessment.

H53 **Has a reassessment been conducted to meet the annual reassessment requirement?**

_____ No

___X___ Yes

H53a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** On December 14, 2011, the HACCP plan was reassessed and changes were made to reflect changes in the Formulation department. The HACCP plan was signed by Jim Whitham on December 14, 2011. He has overall responsibility for the development and implementation of the plan.

H54 **Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?**

___X___ Yes

_____ No significant developments occurred

_____ No

H54a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** On December 14, 2011, the HACCP plan was reassessed and changes were made to reflect changes in the Formulation department. The HACCP plan was signed by Jim Whitham on December 14, 2011. He has overall responsibility for the development and implementation of the plan.

H55 **Has change occurred that could affect the hazard analysis or HACCP plan?**

_____ No

___X___ Yes

H55a **Did the establishment reassess?**

_____ No changed occurred

_____ No

___X___ Yes

H55b **If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately?**

_____ No change occurred

_____ No

___X___ Yes

H55c **For H55-H55b, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.** On December 14, 2011, the HACCP plan was reassessed and changes were made to reflect changes in the Formulation department. The HACCP plan was signed by Jim Whitham on December 14, 2011. He has overall responsibility for the development and implementation of the plan.

Pathogen Reduction and Validation for Salmonella

PRE1 **Does the establishment have a validated process for Salmonella lethality in the HACCP plan?**

___X___ Yes
_____ No

PRE2 **Is the validation documented?**

___X___ Yes
_____ No

PRE2a **The process was validated by:**

___X___ Challenge Study
___X___ Scientific Publication
_____ Modeling Program
___X___ Historical Records
_____ Appendix A, compliance guidelines to 9 CFR 318.17
_____ Other

PRE2a1 **Please specify:**

Insert Text

PRE2b **Did the validation study specify any critical operational parameters (e.g., time, temperature, humidity, water activity, ingredient concentration, pH, etc.)?**

___X___ Yes
_____ No

PRE2b1 **If yes, please describe the critical operational parameters.** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella during Fermentation and Cooking of a Dry Sausage Product. The study was conducted using a pepperoni product mixture and casing provided by the company as well as process parameters used. The results demonstrate that the fermentation is adequate to achieve a pH of at least 5.3 and a ≥6 log reduction in *E. coli* and *Salmonella*. Finished product testing for generic E. coli, coliforms, TPC is also conducted; all results reviewed were negative, further supporting the effectiveness of the process.

PRE2c **If the critical operational parameters were specified, are they being applied in the HACCP plan in a similar manner?**

___X___ Yes

_____ No

PRE2d **Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the intervention?**

___X___ Yes

_____ No

PRE2e **If the critical operational parameters, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective?**

___X___ Yes

_____ No

PRE2f **If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different?**

_____ Yes

___X___ No

PRE3 **Did the establishment initially gather operational data for the adequacy of the process to reduce Salmonella?**

___X___ Yes

_____ No

PRE4 **Why did you come to this conclusion in PRE1-3? Describe the observations and/or documents used to reach the decision.** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella during Fermentation and Cooking of a Dry Sausage Product. The study was conducted using a pepperoni product mixture and casing provided by the company as well as process parameters used. The results demonstrate that the fermentation is adequate to achieve a pH of at least 5.3 and a ≥6 log reduction in *E. coli* and *Salmonella*. Finished product testing for generic E. coli, coliforms, TPC is also conducted; all results reviewed were negative, further supporting the effectiveness of the process.

Pathogen Reduction & Validation -E. coil 0157:H7

PRE1 **Does the establishment produces beef products?**

___X___ Yes

_____ No

PRE1a Does the establishment have a process validated to reduce the level of E. coli O157:H7 by at least 5 logs?

___X___ Yes

_____ No

PRE1b Is the validation documented?

___X___ Yes

_____ No

PRE1c The process was validated by:

___X___ Challenge Study
_____ Scientific Publication
_____ Scientific Publication
_____ Modeling Program
___X___ Historical Records
_____ Other

PRE1d Please specify.

Insert Text

PRE2 Did the validation study specify any critical operational parameters (e.g., time, temperature, humidity, water activity, ingredient concentration, pH, etc.)?

___X___ Yes

_____ No

PRE2a If yes, please describe the critical operational parameters. Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella during Fermentation and Cooking of a Dry Sausage Product. The study was conducted using a pepperoni product mixture and casing provided by the company as well as process parameters used.

PRE2b If the critical variables were specified, are they being applied in the HACCP plan in a similar manner?

___X___ Yes

_____ No

PRE2c **Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the intervention?**

___X___ Yes

_____ No

PRE2d **If the critical operational parameters, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective?**

_____ Yes

___X___ No

PRE2e **If the establishment did not conduct additional validation, did it provide any rationale to explain why the intervention is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different?**

_____ Yes

___X___ No

PRE3 **Did the establishment initially gather operational data for the adequacy of the process to reduce E. coli O157:H7?**

_____ Yes

___X___ No

PRE3a **Why did you come to this conclusion in PRE1-3? Describe the observations and/or documents used to reach the decision.** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella during Fermentation and Cooking of a Dry Sausage Product. The study was conducted using a pepperoni product mixture and casing provided by the company as well as process parameters used. The results demonstrate that the fermentation is adequate to achieve a pH of at least 5.3 and a ≥6 log reduction in *E. coli* and *Salmonella*. Finished product testing for generic E. coli, coliforms, TPC is also conducted; all results reviewed were negative, further supporting the effectiveness of the process. The establishment samples finished product and tests it in-house for generic *E. coli*, coliforms, *Staphylococcal* Enterotoxin, and total plate count using 3M Petri films. Results from 2011 were reviewed; all results were within established limits. In addition, at a customer's request, product is sent to a third party lab and tested for *Staphylococcus aureus* (AOAC 975.55) and *Listeria* spp. (AOAC 020401).

Sampling and Testing

ST1 **Does the establishment test finished product for E. coli O157:H7?**

___X___ Yes

_____ No

_____ **Establishment does not produce beef products**

ST1a **Have any products tested positive for E. coli O157:H7?**

_____ **Yes**

___X___ **No**

ST1b **Why did you come to this conclusion in? Describe the observations and/or documents used to reach the decision.** In discussion with Jim Whitham, it was determined that finish product testing is being conducted per customer request however; this is not outlined in any written program. Mr. Whitham stated only two samples have been submitted for testing of 01/11/2012. The third party analytical results from May 17, 2011 and December 20, 2011 for review and found negative for *E. coli* O157:H7. The lab reports indicate a 25g sample was analyzed using AOAC RI method 010401 (PCR).

ST2 **Does the establishment test finished product for Salmonella?**

___X___ **Yes**

_____ **No**

ST2a **Have any products tested positive for Salmonella?**

_____ **Yes**

___X___ **No**

ST2b **Does the establishment serotype samples positive for Salmonella?**

_____ **Yes**

___X___ **No**

ST2c **If positive for Salmonella, was the serotype one of the current top 30 serotypes associated with human illness as listed by CDC?**

_____ **Yes**

___X___ **No**

ST2d **If yes, list serotypes.** In discussion with Jin Whitham it was determined that the company would not serotype positives unless requested by a customer.

ST3 **Does the establishment test finished product for other pathogens?**

___X___ **Yes**

_____ **No**

ST3a **If so, what pathogens?** The establishment samples finished product and tests it in-house for generic *E. coli*, coliforms, *Staphylococcal* Enterotoxin, and total plate count using 3M Petri films. Results from 2011 were review; all results were within established limits. In addition, at a customer's request, product is sent to a third party lab and tested for *Staphylococcus aureus* (AOAC 975.55) and *Listeria* spp. (AOAC 020401).

ST3b **Have any products tested positive for those pathogens?**

_____ Yes

___X___ No

ST4 **Using the FSIS method for comparison, is the sampling and testing procedure adequate to detect low levels of *E. coli* O157:H7 or *Salmonella* contamination in every lot?**

_____ Yes

___X___ No

ST4a **Why did you come to this conclusion in? Describe the observations and/or documents used to reach the decision.** Testing is conducted per customer request and is not part of any written program. The frequency of testing is unknown. This sampling activity is not intended to represent every lot and is not used as justification for decisions made in the hazard analysis.

ST5 **Does the establishment holds the sampled lot of product pending test results?**

___X___ Yes

_____ No

ST6 **Has the establishment had a positive sample for E. coli O157:H7 or Salmonella from FSIS testing?**

_____ Yes

___X___ No

ST7 **Has there ever been a recall associated with *E. coli* O157:H7 or *Salmonella* in the finished products produced by the establishment?**

_____ Yes

___X___ No

S8 **Does the plant have corrective action procedures in place when a sample is positive for *E. coli* O157:H7 or *Salmonella*?**

_____ Yes

___X___ No

ST9 **Are the corrective actions taken in response to a positive sample for a pathogen recorded?**

_____ Yes

___X___ No

S10 **Are measures developed to prevent the recurrence of a sample positive for a pathogen?**

_____ Yes

___X___ No

_____ Please describe

ST10a **Briefly describe the corrective action procedures, adequacy, and history of implementation.**
LEARN Data was reviewed and in discussion with FSIS IPP, there have been no positive results. The company does not have written corrective actions if product would be found positive for a pathogen however, product is held pending test results.

Post-lethality Treatment (PLT)

PLT1 **Has the establishment validated and documented the PLT?**

___X___ Yes

_____ No

PLT1a **Does the validation identify any critical operational parameters (e.g., time, temperature, or pressure of the PLT, ingredient concentration limits for the PLT to be effective, pH of the raw or finished product, etc.)?**

___X___ Yes

_____ No

PLT1b **If the critical operational parameters have been identified for the PLT, is the establishment applying those critical variables in a manner similar to that described in the validation?**

___X___ Yes

_____ No

PLT1c **Is the product or product formulation used by the establishment the same as or similar to the product or product formulation in the validation study?**

___X___ Yes

_____ No

PLT1d **If the critical operational parameters, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective?**

___X___ Yes

_____ No

PLT1e **If the establishment did not conduct additional validation, did it provide any rationale to explain why the PLT is effective and has the same impact even though the critical operational parameters, product formulation, procedure or equipment are different?**

_____ Yes

___X___ No

PLT1f **Why did you come to these conclusions? Describe the observations and/or documents used to reach the decision.** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

PLT2 **Did the establishment initially gather data to demonstrate the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions as stated in the HACCP plan?**

_____ Yes

___X___ No

PLT2a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

PLT3 **Does the establishment have a rational basis or data to show that the reduction of *Lm* by the PLT as described is sufficient to control the level of contamination of Lm that may occur in the product?**

___X___ Yes

_____ No

PLT3a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Water activity of finished product (<0.85) as well as pH (<4.6) monitoring is conducted. Historical data indicates the process results in product characteristics that will not support the growth of *Lm.*

PLT4 **If the level of contamination is in excess of that expected during the operation of well-maintained plant with adequate sanitation procedures (e.g., standing water, roofs leaks, construction), does the establishment have documentation that the PLT is still effective?**

___X___ Yes

_____ No

PLT4a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The company does have test results showing the incoming load on raw product as well as environmental and finished product test results that demonstrate the bacterial loads on the product and in the environment are within the established limits. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

PLT5 **If rework is used, does the establishment have documentation that the level of contamination below that for which the intervention is designed?**

_____ Yes

___X___ No

_____ Rework not used

PLT5a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The company does have test results showing the incoming load on raw product as well as environmental and finished product test results that demonstrate the bacterial loads on the product and in the environment are within the established limits. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

PLT6 **Is the PLT treatment a pre-packaging treatment, i.e., the PLT is applied after environmental exposure but before re-packaging (e.g., infrared treatment)?**

_____ Yes

___X___ No

PLT7 **If the PLT is a pre-packaging PLT, does the establishment have validated control measures in place to prevent recontamination after treatment and before re-packaging?**

_____ Yes

___X___ No

PLT7a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** The process includes fermentation and heat treatment. Records reviewed indicate

the process consistently results in products with a pH ≤4.6.

Antimicrobial Agents and Processes (AMAP)

AM1 Has the establishment validated and documented the AMAP?

___X___ Yes

_____ No

AM1a Did the validation identify any critical operational parameters (e.g., moisture levels for finished product when using antimicrobial agents such as lactate and diacetate, pH of the finished product or pH during preparation, water activity of the finished product, etc.)?

___X___ Yes

_____ No

AM1a1 If yes, please describe the critical operational parameters. . Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

AM1b If the critical operational parameters have been identified for the AMAP, is the establishment controlling those critical operational parameters in a manner the same or similar to that described in the validation?

___X___ Yes

_____ No

AM1c Is the establishment using the AMAP as described in the validation with regards to equipment and procedures?

___X___ Yes

_____ No

AM1d If the critical operational parameters, product formulation, procedures or equipment used by the establishment are not exactly the same as those used in the validation, did the establishment conduct additional validation that demonstrated that the changes are effective and produce the same or better result?

___X___ Yes

_____ No

AM1e **Is the product formulation used by the establishment the same or similar to the product or product formulation used in the validation study using the AMAP?**

___X___ Yes
_____ No

AM1f **If the establishment did not conduct additional validation, did it provide any rationale to explain why the treatment is effective and has the same effect even though the critical operational parameters, product formulation, procedure or equipment are different?**

_____ Yes
___X___ No

AM1g **Why did you come to this conclusion in AM1a-f? Describe the observations and/or documents used to reach the decision. .** Initial validation of the HACCP plan was not available for review. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

AM2 **Did the validation study or validation of the model include a shelf life study, i.e., determining the growth of LM during storage?**

_____ Yes
___X___ No

AM2a **Is the refrigerated shelf life (use by date on the label) the same or longer than the recommended shelf life in the validation?**

_____ Yes
___X___ No

AM2b **Why did you come to this conclusion in AM2 and AM2a? Describe the observations and/or documents used to reach the decision.** The HACCP plan identifies the shelf life as 9 months >40°F and indefinite if refrigerated or frozen. No shelf life studies were provided for review however, the product will not support the growth of *Lm* if the water activity is ≤0.85 and has a pH ≤4.6.

AM3 **Did the establishment initially gather data to demonstrate the adequacy of the AMAP in inhibiting Lm growth?**

_____ Yes
___X___ No

AM4 **Does the establishment have a rational basis or data to show that the level of growth allowed by**

the AMAP is sufficient to control Lm growth in the product?

___X___ Yes
_____ No

AM5 **If the level of contamination is in excess of that expected during the operation of well-maintained plant with adequate sanitation procedures (e.g., standing water, roofs leaks, construction), does the establishment have documentation that the AMAP is still effective?**

_____ Yes
___X___ No

AM5a **Why did you come to this conclusion in AM3-5? Describe the observations and/or documents used to reach the decision.** The company does have test results showing the incoming load on raw product as well as environmental and finished product test results that demonstrate the bacterial loads on the product and in the environment are within the established limits. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 and titled Validation of Inactivity of Escherichia coli O157:H7 and Salmonella During Fermentation and Cooking of a Dry Sausage Product. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

AM6 **If rework is used, does the establishment have documentation that the level of contamination is below that for which the intervention is designed?**

___X___ Yes
_____ No
_____ Rework not used

Sanitation

S1 **Are traffic patterns established to eliminate movement of personnel and equipment between the raw and RTE areas or controlled to prevent cross-contamination?**

___X___ Yes
_____ No

S1a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Review of the establishment's programs and observations made during the assessment indicated that movement of personnel and equipment between the raw and RTE areas are controlled. Raw and RTE employees are not totally segregate throughout the facility however, the production areas are separated. Employees are required to pass through a boot scrubber and/or foot foamer, and color-coded frocks are used and remain in the specific production area. Employees are required to stay in their production area; if employees move between departments, they must change their frock.

S2 **Are the raw and RTE areas physically separated (e.g., by a wall, etc.)? If not, is the potential for cross contamination minimized?**

___X___ Yes
_____ No

S2a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Review of the establishment's programs and observations made during the assessment indicated that the raw and RTE areas are separated by doors and walls; however, there are commonly traveled areas of the facility. The establishment has multiple foot foamers in place to control cross-contamination throughout the facility.

S3 **Does the establishment limit the use of garments and utensils to specific areas (e.g., garments used in the RTE areas restricted to the RTE areas?)**

___X___ Yes
_____ No

S3a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Review of the establishment's programs and observations made during the assessment indicated that white frocks are designated for RTE areas and blue frocks in raw areas; the establishment also maintains different utensils for use in the raw and RTE areas.

S4 **Are equipment and tools for maintenance sanitized before use in another area if only one set of tools is available?**

___X___ Yes
_____ No

S4a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Based on review of the written programs and observations, tools are intended to be used in the area in which they are located. Tools are included in the environmental testing program. All test results have been negative.

S5 **Are all materials for discard (trash and waste) removed at clean up (mid-shift, end-shift, etc.)?**

___X___ Yes
_____ No

S6 **Is equipment, such as slicers and dicers, with blades disassembled for thorough cleaning at the end of the operation?**

___X___ Yes
_____ No

S7 **Is equipment cleaned at the end of operation to remove food and other debris?**

___X___ Yes
_____ No

S8 **Are equipment and floors sanitized after being rinsed?**

___X___ Yes
_____ No

S9 **Is sanitizer for equipment and floors used in the concentration specified where used?**

___X___ Yes
_____ No

S9a **Why did you come to this conclusion in questions S5-S9? Describe the observations and/or documents used to reach the decision.** Review of the establishment's programs and observations made during the assessment indicated the company has an employee designated to remove trash and product on the floor during production. Pre-operational sanitation procedures and monitoring was observed on January 12, 2012. Equipment that can be disassembled is during cleaning. Sanitizer is applied after cleaning procedures were conducted. Sanitizer concentration is monitored by the Sanitation Supervisor via litmus paper. The concentration was observed being used at the manufacturer's recommendation strength.

S10 **Are operations discontinued during construction, or are the areas under construction or remodeling isolated to prevent contamination of other areas of operation?**

___X___ Yes
_____ No

S10a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Construction was not being conducted during the assessment however; the company does have a construction program in place. The area under construction will be segregated and will prompt intensified cleaning and/or sampling if conducted in high-risk RTE areas.

S11 **Are conditions that may contribute to product and food contact surface contamination (e.g., standing water) corrected as soon as possible?**

___X___ Yes
_____ No

S11a **Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision.** Observation of production practices during the assessment indicates sanitary conditions are maintained to ensure product contamination does not occur.

S12 **Does the sanitation program or prerequisite program provide for testing FCS in the post-lethality processing environment in compliance with 9 CFR 430?**

___X___ Yes
_____ No

S13 **Does the sanitation program or prerequisite program identify the conditions under which the establishment will implement hold-and-test procedures following a FCS test that is positive for Listeria-like, Listeria spp., or L. monocytogenes in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S14 **Does the sanitation program or prerequisite program state the frequency (includes both how many samples and when samples are collected) for testing in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S15 **Does the sanitation program, prerequisite program or other recordkeeping system identify the location of sites for sampling in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S16 **Does the sanitation program or prerequisite program identify the size of sites for sampling in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S17 **Are the selected locations of the sites the most probable area for contamination?**

___X___ Yes

_____ No

S18 **Are all possible FCS sampling sites identified in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S19 **Does the sanitation program or prerequisite program explain why the testing frequency is sufficient to ensure effective control of Listeria-like, Listeria spp., or L. monocytogenes in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S19a **Why did you come to this conclusion in S12-S19? Describe the observations and/or documents used to reach the decision.** All products produced at this facility are RTE and post lethality exposed. The product is produced under Alternative 1 per 9 CFR 430. The company maintains a program titled Environmental Testing Program, which includes the sampling frequency, sites,

method, and explanation of frequency selection. Each RTE lines will be sampled quarterly and include 3 FCS and 3 ICS. The sample locations identified are adequate and one square foot will be sampled if possible. The frequency is based on plant history. Results reviewed indicate multiple samples are collected weekly. Sample collection was observed and conducted be the written program. The programs states that if a FCS is found positive the same location and two additional sites will be sampled during pre-op and three additional samples will be taken x2 during production and affected product will be held. A 2nd positive will result in product being held and tested.

S20 **Has the plant ever had a FCS test positive for Listeria-like, Listeria spp., or L. monocytogenes?**

___X___ Yes

_____ No

S20a **If a FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were the hold-and-test procedures implemented as written in the sanitation program in compliance with 9 CFR 430?**

___X___ Yes

_____ No

S20b **If FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were measures taken to prevent recurrence?**

___X___ Yes

_____ No

S20c **If FCS tested positive for Listeria-like, Listeria spp., or L. monocytogenes, were corrective actions taken to identify and eliminate the source of contamination?**

___X___ Yes

_____ No

S20d **If a FCS tested positive for L. monocytogenes, was the lot of product affected destroyed or reworked with a process that eliminates L. monocytogenes?**

___X___ Yes

_____ No

S20e **Were the results of the follow-up product testing documented?**

_____ Yes

___X___ No

S2f **Were non-FCS tested in follow-up sampling for Listeria-like, Listeria spp., or L. monocytogenes?**

___X___ Yes

_____ No

S20g **Was follow-up testing conducted on the FCS site that tested positive for Listeria-like, Listeria spp., or L. monocytogenes to verify that the corrective actions after an initial positive test on a FCS were effective?**

___X___ Yes

_____ No

S20h **Was follow-up testing conducted on the FCS area surrounding the FCS site that tested positive for Listeria-like, Listeria spp., or L. monocytogenes to verify that the corrective actions after an initial positive test on a FCS were effective?**

___X___ Yes

_____ No

S20i **If a second follow-up FCS tested positive for Listeria-like or Listeria spp. on follow-up testing, were lots of affected products held?**

_____ Yes

___X___ No

S20j **If the second follow-up FCS tested positive for Listeria-like, Listeria spp. on follow-up testing, were the affected lots of product tested for Listeria-like, Listeria spp. or L. monocytogenes?**

_____ Yes

___X___ No

S20k **If a second follow-up FCS tested positive for L. monocytogenes on follow-up testing, were the affected lots of product destroyed or reworked with a process that is destructive of L. monocytogenes?**

_____ Yes

___X___ No

S20l **If the second follow-up FCS tested positive for Listeria-like or Listeria spp. on follow-up testing, did the sampling method and frequency provide a level of statistical confidence that ensured that each lot was not adulterated with L. monocytogenes?**

_____ Yes

___X___ No

Analysis

A1 **Briefly describe any findings (positive and negative) concerning 03F plans not addressed in the**

previous questions. The Environmental Swabbing Reports generated from June1, 2011 through December 28, 2011 were reviewed. This report is used to document Listeria spp. results for swabs collected from food contact and environmental sites. The records indicate on October 27, 2011 the sample collected from Slicer #2 Short/Long Conveyor was positive. The company identified a cause and implemented appropriate corrective actions. The record indicates all affected product was destroyed. In addition, follow-up testing was negative.

A2 Analysis and Summary: Please discuss findings (positive and negative) and any regulatory noncompliance associated with HACCP 03F plans at this establishment using the relevant data gathered above. Include in your discussion how the findings impact the establishment's ability to meet the requirements of the FMIA/PPIA and that impact on food safety. Documents reviewed at Liguria Foods, indicate a hazard analyses was conducted to determine the food safety hazards reasonably likely and not reasonably likely to occur in their process. The Shelf Stable Dry Sausage HACCP Plan was reviewed, all hazards reasonably likely to occur are appropriately identified, and sufficient controls are in place.

The company conducts raw product testing as well as environmental and finished product testing demonstrating the bacterial loads on the product are not excessive, sanitation procedures are adequate and finished products are within the established limits. A challenge study was conducted by Silliker, Inc. Food Science Center in July 2011 to validate the current process. The study was conducted to demonstrate that the fermentation and heat treatment is adequate to achieve a pH of at least 5.3 and a 6-log reduction in E. coli and Salmonella. Data reviewed indicates the process employed is sufficient to achieve the desired pH and heat treatment necessary to produce a safe product.

Review of the HACCP plan and associated supporting documents indicate the HACCP plan has been adequately developed with the following exceptions; The HACCP plan does not include direct observation of corrective actions. Also the written program states: "reviews will be considered to be successful if a NR/deviation report is not filled out". The HACCP records do not include results as required. A noncompliance with 9 CFR 417.2(c)(7) and 9 CFR 417.5(a)(3) which were documented on XXXX.

The noncompliance observed do not result in food safety concerns based on observation that procedures are being appropriately implemented. Based on all information reviewed the company has developed an adequate food safety system sufficient to produce safe and wholesome product supporting the recommendation that noncompliance found be addressed with a NR.